

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>5189</b>
		U.S. APPLICATION NO. <b>10/580124</b> (If known, see 37 CFR 1.5)
INTERNATIONAL APPLICATION NO. <b>PCT/US2005/002609</b>	INTERNATIONAL FILING DATE <b>January 27, 2005 (01.27.2005)</b>	PRIORITY DATE CLAIMED <b>January 27, 2004 (01.27.2004)</b>
TITLE OF INVENTION <b>Pituitary Adenylate Cyclase Activating Peptide (PACAP) Receptor (VPAC2) Agonists and Their Pharmacological Methods of Use</b>		
APPLICANT(S) FOR DO/EO/US <b>Kevin Clairmont, et al.</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p style="margin-left: 20px;">d. <input checked="" type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <b>[Copy of Declaration of the Inventors from PCT Request]</b></p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p>		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

(PTO-1390 (Rev. 07-2005))

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/586124		PCT/US2005/002609		5189	
20. Other items or information: <ol style="list-style-type: none"> <li>1) Certificate of Mailing under 37 C.F.R. 1.10</li> <li>2) Sequence Listing Transmittal and one (1) diskette for submission under 37 C.F.R. 1.821(e)</li> <li>3) Copy of the International Search Report</li> <li>4) Itemized Return Receipt Postcard</li> </ol>					
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))					
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0				\$ 200.00	
All other situations..... \$200					
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))					
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100				\$ 100.00	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400					
All other situations..... \$500					
TOTAL OF 21, 22 and 23 =				\$600.00	
<input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
110 - 100 =	10 /50 =	1	x \$250	\$ 250.00	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	53 - 20 =	33	x \$ 50	\$ 1,650.00	
Independent claims	33 - 3 =	30	x \$200	\$ 6,000.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			0 + \$360	\$ 00.00	
TOTAL OF ABOVE CALCULATIONS =				\$ 8,500.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/3.					
SUBTOTAL =				\$ 8,500.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
TOTAL NATIONAL FEE =				\$ 8,500.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$ 8,500.00	
				Amount to be refunded:	\$
				Amount to be charged	\$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 13-3372 in the amount of \$ 8,500.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 13-3372. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO: **Customer No. 35969**

**Jeffrey M. Greenman**  
Vice President  
Patents and Licensing  
Bayer Pharmaceuticals Corporaton  
400 Morgan Lane  
West Haven, CT 06516

*Susan M. Pellegrino*  
\_\_\_\_\_  
SIGNATURE

**Susan M. Pellegrino**  
\_\_\_\_\_  
NAME

**48,972**  
\_\_\_\_\_  
REGISTRATION NUMBER

**Date of Deposit: 14 July 2006**  
**Express Mail Label Number: EQ 390 598 755 US**

Attorney's Docket No. 5189

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kevin CLAIMONT, et al.

Serial No.: [to be assigned] National Stage Filing of PCT/US2005/002609

Filed: herewith

For: Pituitary Adenylate Cyclase Activating Peptide (PACAP) Receptor (VPAC2) Agonists and  
Their Pharmacological Methods of Use

MAIL STOP PCT  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR 1.10

I hereby certify that the *attached* correspondence comprising:

- ☒ Transmittal Letter to the United States Designated/Elected Office (DO/EO/US)  
Concerning a Filing under 35 U.S.C. 371 [IN DUPLICATE]
- ☒ Application Data Sheet under 37 C.F.R. 1.76
- ☐ Preliminary Amendment
- ☒ Copy of oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4))
- ☐ English Translation of the Application (35 U.S.C. 371(c)(2))
- ☒ Copy of the International Application as filed (35 U.S.C. 371(c)(2))
  
- ☒ Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98 consisting of:
  - 1) Transmittal of Information Disclosure Statement under 37 C.F.R. 1.97(b)(2)
  - 2) Form(s) PTO/SB/08A-B [substitute for form 1449/PTO] (37 C.F.R. 1.98(a)(b))
  - 3) Copies of Cited References (37 C.F.R. 1.98(d))
- ☒ Other:
  - 1) Sequence Listing Transmittal and one (1) diskette for submission under 37 C.F.R. 1.821(e)
  - 2) Printout of the Sequence Listing
  
- ☒ Itemized Return Receipt Post Card

is, on the date shown below, being deposited with the United States Postal Service, in an envelope  
as "Express Mail Post Office to Addressee" Mailing Label Number EQ 390 598 755 US  
addressed to:

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

14 July 2006  
Date

  
Signature of Person Certifying / Gil Cunha